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# Guidance for the Reregistration of Pesticide Products Containing Dicofol as the Active Ingredient

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# GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING
DICOFOL
AS THE ACTIVE INGREDIENT

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
WASHINGTON, D.C. 20460
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# TABLE OF CONTENTS

Introduction . . . . . . . . . . . . . . . . . . . . . . . . iii

I. Regulatory Position. . . . . . . . . . . . . . . . . . . . . 1

II. Requirement for Submission of Generic Data . . . . . . . . 20

III. Requirement for Submission of Product-Specific Data . . . . . . . . . . . . . . . . . . . . . . . . 23

IV. Submission of Revised Labeling and Packaging Information. . . . . . . . . . . . . . . . . . . . . . . 49

A. Label Contents . . . . . . . . . . . . . . . . . . . . 49

1. Product Name . . . . . . . . . . . . . . . . . . . . 49
2. Company Name and Address . . . . . . . . . . . . . 49
3. Net Contents . . . . . . . . . . . . . . . . . . . . 49
4. Product Registration Number. . . . . . . . . . . . 50
5. Producing Establishment Registration Number. . . . . . . . . . . . . . . . . 50
6A Ingredient Statement . . . . . . . . . . . . . . . 50
6B Pounds Per Gallon Statement. . . . . . . . . . . . 50
7. Front Panel Precautionary Statements . . . . . . . 50
7A Child Hazard Warning Statements. . . . . . . . . . 51
7B Signal Word. . . . . . . . . . . . . . . . . . . . 51
7C Skull and Crossbones and Word Poison . . . . . . . 51
7D Statement of Practical Treatment . . . . . . . . . 51
7E Referral Statement . . . . . . . . . . . . . . . . 51
8. Side/Back Panel Precautionary Labeling . . . . . . 51
8A Hazard to Humans and Domestic Animals. . . . . . . 52
8B Environmental Hazard . . . . . . . . . . . . . . . 52
8C Physical or Chemical Hazard. . . . . . . . . . . . 52
9 Misuse Statement . . . . . . . . . . . . . . . . . 53
10A Storage and Disposal Block . . . . . . . . . . . . 53
10B Directions for Use . . . . . . . . . . . . . . . . 53

B. Collateral Information . . . . . . . . . . . . . . . . 53

V. Instructions for Submission. . . . . . . . . . . . . . . . 54

# APPENDICES

I Bibliography. . . . . . . . . . . . . . . . . . . . . . 55

II FIFRA §3(c)(2)(B) Summary Sheet - EPA Form 8580-1 . . 66

III Certification of Attempt to Enter Into an Agreement With Other Registrants for Development of Data EPA Form 8580-6 . . . . . . . . . . . . . . . . . . . . . 67

IV Product Specific Data Report (End-Use Products) EPA Form 8580-4 . . . . . . . . . . . . . . . . . . . . . 68

V-2 Table of Labeling Requirements and Sample Labels. . . 70

V-3 Physical/Chemical Hazards Labeling Statement. . . . . 74

V-4 Storage and Disposal Instructions . . . . . . . . . . 75

Note: Appendices V-1, V-5 and V-6 are not germane to this document and are not included.

Also attached to this document are copies of the letters sent to registrants to transmit this document and notify them of studies required.

# INTRODUCTION

The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA Section 3(g), as amended in 1978 directs EPA to reregister all pesticides as expeditiously as possible. Each registrant of a manufacturing use product of the active ingredient who wishes to continue to sell or distribute that product must apply for reregistration.

To fulfill this Congressional mandate, we have established the Registration Standards program which will review all pesticide active ingredients first registered before January 1, 1977. These pesticides will be reviewed in use clusters which are prioritized on the basis of a ranking scheme giving preference to pesticides used on food and feed crops.

The Registration Standards program involves a thorough review of the scientific data base underlying pesticide registrations and an identification of essential but missing studies which may not have been required when the product was initially registered or studies that are now considered insufficient. Our reassessment results in the development of a regulatory position, contained in this document, on each pesticide and its uses. The regulatory position may require the registrant to modify product labels to provide additional precautionary statements, restrict the use of the pesticide to certified applicators, provide reentry intervals, modify uses or formulation types, specify certain packaging limitations, or other requirements to assure that proper use of the pesticide poses no potential adverse effects to human health or the environment.

The scientific review, which is not contained herein but is available upon request, concentrates on the technical grade of the active ingredient and identifies missing generic data. However, during the review of these data we are also looking for potential hazards that may be associated with the formulated (end-use) products that contain the active ingredient. If we find serious concerns, we will bring formulated products under the provisions of the Registration Standards program to the extent necessary to protect the public.

EPA has the authority under FIFRA §3(c)(2)(B) to require that certain registrants submit generic data that will answer our questions regarding the hazard that may result from the intended use of the pesticide under review. Further, §3(c)(2)(B) provides that these data are to be submitted by those registrants who do not qualify for the formulator's exemption [FIFRA §3(c)(2)(D)]. Normally, this means that the registrants who are responsible for filling the data gaps are the manufacturing-use product producers (basic suppliers of the active ingredient). However, end-use producers will not qualify for the formulator's exemption if the source of their active ingredient: (1) is not registered with EPA, and/or (2) is produced by the registrant's firm or a firm which has ownership in common with the registrant's firm. These end-use producers can qualify for the formulator's exemption if they change their source of supply to a registered source, provided the source does not share ownership in common with the registrant's firm. If the end-use product registrant decides to switch sources, a new Confidential Statement of Formula, EPA Form 8570-4, must be submitted to the appropriate Product Manager within 90 days of receipt of this Guidance Document. The chart on the following page shows what is generally required of those who do and do not qualify for the formulator's exemption in the Registration Standards program.

If you decide to request the Agency to discontinue the registration of any of your products subject to the reregistration requirements of this Guidance Document, please notify the Product Manager named in the cover letter, within 90 days from the receipt of this document, that you wish to voluntarily cancel the registration(s). If you decide to maintain your product registration(s), you must provide the information described in the following pages within the timeframes outlined. EPA will issue a notice of intent to cancel or suspend the registration of any currently registered product if you fail to comply with the requirements set forth in this Guidance Document.

This Guidance Document will be supplemented by EPA with additional information about compliance with data support requirements. In Monsanto v. Administrator, EPA was recently enjoined from implementing in any way the "mandatory data licensing" aspects of §3(c)(1)(D) of FIFRA. EPA is assessing the implications of the injunction for the reregistration process. Because this situation is currently unresolved, EPA has decided to proceed with the requirements in this Guidance Document which do not relate to compliance with the §3(c)(1)(D) provisions and to supplement the Document with additional guidance when circumstances permit. Failure to comply with the provisions of the subsequent guidance will also result in issuance by EPA of an intent to cancel the affected product registration(s).

Registrants are reminded that §6(a)(2) of FIFRA requires you at any time to submit factual information raising concerns of possible unreasonable adverse effects of a pesticide. You should notify the Agency of interim results of studies in progress if those results show possible adverse effects.

| PRODUCTS SUBJECT TO THE REGISTRATION STANDARDS PROGRAM | ACTION(S) REQUIRED TO MAINTAIN REGISTRATION |
|---|---|
| I. Products That Do Not Qualify For The Formulator's Exemption | |
| A. Single Active Ingredient Products* | These products must be reregistered. To obtain reregistration, labeling, packaging and data requirements must be satisfied in accordance with the Registration Standards Guidance Document. |
| B. Multiple Active Ingredient Products | These products will not be reregistered at this time. However, generic data required to continue the registration of the active ingredient under review, as described in the Registration Standards Guidance Document, will be required and some labeling precautions may also be required. |
| II. Products That Do Qualify For The Formulator's Exemption | Only when additional restrictions or labeling are needed to protect man or the environment will these products be subject to the Registration Standard requirements. Affected products will be dealt with in a variety of ways, including but not limited to the Label Improvement Program and special intent to cancel notices. |

* End-use products of registrants who also produce a manufacturing-use product will not be required to be reregistered provided that registrant fulfills the requirements specified in the Guidance Document for manufacturing-use product(s). Such end-use products will be subject to the labeling changes required for products in "II" above. If there are no manufacturing-use products registered by any company end-use products will be required to be reregistered.

NOTE: If all registrants in "I" above fail to meet the requirements in I-A and B above, then the registrants in "II" lose their right to qualify for the formulator's exemption and become subject to the requirements in I-A and B.

# I. REGULATORY POSITION AND RATIONALE

A. Introduction
B. Chemical Description and Use Summary
C. Regulatory Position
D. Regulatory Rationale
E. Criteria for Registration and Reregistration under this Document
F. Acceptable Ranges and Limits
G. Required Labeling
H. Tolerance Reassessment
I. Special Studies

## A. INTRODUCTION

This Guidance Document describes the Agency's regulatory position on manufacturing-use products containing dicofol. The Agency's position addresses a number of regulatory requirements -- labeling requirements, tolerances, and the data requirements -- that must be met to register or reregister products covered by this Guidance Document.

As part of developing its regulatory position on a pesticide, the Agency makes a determination whether any of the criteria in 40 CFR 162.11 have been met and whether a Special Review[1/] should be initiated. This document serves to notify the registrants that a Special Review will be initiated. The Special Review process will be explained briefly below, as well as the Agency's concerns and rationale for initiating the Special Review.

In addition to the basic regulatory decision and rationale, this Document includes the following: criteria for the registration or reregistration of

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[1/] Special Review is the new name for the Rebuttable Presumption Against Registration (RPAR) process. This name will be proposed in regulations in the near future.

dicofol products under the Guidance Document; acceptable ranges and limits for product composition, acute toxicity and use patterns; required labeling; and a tolerance reassessment.

## B. CHEMICAL DESCRIPTION AND USE SUMMARY

The chemical name for dicofol is 1,1-bis(chlorophenyl)-2,2,2-trichloroethanol; for convenience in writing this Guidance Document, the name dicofol will be used instead of the chemical name. Use of the name dicofol implies no endorsement of any product containing the active ingredient. There is no common name for the chemical accepted by the American National Standard Institute.

The Chemical Abstracts Registry (CAS) number for dicofol is 115-32-2. The EPA Shaughnessey number is 010501. The chemical formula is $C_{14}H_9Cl_5O$, and the molecular weight is 370.51.

Trade names and other names for dicofol include: Acarin®, Carbax®, CAS 115-32-2, CPCA, Decofol®, Dichlorokelthane, DTMC, ENT-23648, FW-293, Kelthane®, Kelthane A®, p,p'-Kelthane, Kelthanethanol, Mibol®, Mitigan®, and NCI-000486. Other chemical names for dicofol are:

1. Benzenemethanol, 4-chloro-alpha-(4-chlorophenyl)-alpha-(trichloromethyl)-
2. Benzhydrol, 4,4'-dichloro-alpha-(trichloromethyl)-
3. 1,1-Bis(4-chlorophenyl)-2,2,2-trichloroethanol
4. 4,4'-Dichloro-alpha-(trichloromethyl)benzhydrol
5. Di-(p-chlorophenyl)trichloromethylcarbinol
6. 2,2,2-Trichloro-1,1-di(4-chlorophenyl)ethanol

Manufacturing-use dicofol is a non-flowable liquid (or waxy solid) at room temperature. It ranges from dark to yellow-brown in color. It is stable under cool and dry conditions, and is practically insoluble in water, but readily soluble in most organic solvents. Its melting point ranges from 58°C to 78°C.

Dicofol was first registered as a pesticide in 1957. Manufacturing-use dicofol products are not produced domestically. Rather, all dicofol used in domestically registered pesticides is imported. Dicofol is used in acaricides to control mites on agricultural crops and ornamentals and in or around agricultural and domestic buildings. End-use products containing dicofol are made in a variety of formulations, and marketed as emulsifiable concentrates, wettable powders, dusts, ready-to-use liquids, and aerosol sprays. The products act on the surfaces of the sites of application to control mites.

There are currently six registered manufacturing-use products consisting of the technical grade of dicofol (80 - 85%) and four formulation intermediates, one of which is a multiple active ingredient product. There are seven registered manufacturers of these manufacturing-use products: Rohm and Haas Company, Makhteshim Beer-Shiva, Aceto Chemical Company, Agan Chemical Manufacturers, Drexel Chemical Company, Tricon Chems International, and Ida, Inc.

End-use products containing dicofol as their sole active ingredient include 66 section 3 Federal registrations and 37 Intrastate products. End-use products containing dicofol plus other active ingredients include 130 section 3 Federal registrations and 49 Intrastate products.

Certain unintentional impurities have been identified in manufacturing-use dicofol products which are the result of the manufacturing process. The identified contaminants of concern include the p,p' and o,p' isomers of DDT, DDE, DDD (TDE), and a compound known as "extra-chlorine DDT" (Cl-DDT). The chemical names for these contaminants are as follow:

1. 1,1-bis-(p-chlorophenyl)-2,2,2-trichloroethane [p,p' DDT]
2. 1-(p-chlorophenyl)-1-(o-chlorophenyl-2,2,2-trichloroethane [o,p' DDT]
3. 1,1-bis-(p-chlorophenyl)-2,2-dichloroethylene [p,p' DDE]

4. 1-(p-chlorophenyl)-1-(o-chlorophenyl)-2,2-dichloroethylene [o,p' DDE]
5. 1,1-bis-(p-chlorophenyl)-2,2-dichloroethane [p,p' DDD]
6. 1-(p-chlorophenyl)-1-(o-chlorophenyl)-2,2-dichloroethane [o,p' DDD]
7. 1,1-bis-(p-chlorophenyl)-1,2,2,2-tetrachloroethane [p,p' Cl-DDT]
8. 1-(p-chlorophenyl)-1-(o-chlorophenyl)-1,2,2,2-tetrachloroethane [o,p' Cl-DDT]
9. 1-(2,4-dichlorophenyl)-2-(4-chlorophenyl)-1,2,2,2-tetrachloroethane
10. 1-(2,4-dichlorophenyl)-2-(4-chlorophenyl)-1,,2,2-tetrachloroethane

In this Document, the term DDTr will be used to denote any or all of these DDT analogs. Though an environmental effects and fate data base for Cl-DDT is unavailable, the Agency assumes that this chemical is potentially a DDE precursor.

## C. REGULATORY POSITION

Based upon a review and evaluation of all available data and other relevant information on dicofol, the Agency has made the following determinations:

1. The Agency has determined that the risk criterion in 40 CFR 162.11 regarding an adverse wildlife effect has been met by certain outdoor uses of dicofol products. These products appear to contain a sufficient quantity of DDT contaminants to cause significant adverse ecological effects. The Agency focused on the potential to cause eggshell thinning in documenting the basis for Special Review but recognizes, and is gathering evidence about, a wide range of other effects associated with DDT and related compounds. A Special Review of all outdoor dicofol end-use products containing detectable amounts of DDTr will be initiated.

2. No new registrations for dicofol products intended for outdoor use will be issued which would further increase the amount of DDTr in the environment.

3. Registrants and applicants for registration of manufacturing-use dicofol products must provide or agree to develop the additional data specified in Tables A and B of this Document in order to maintain existing registrations. Tables A and B include special studies, explained in Section I below, which are needed to address the concerns above. The health effects data required must be conducted and submitted in accordance with the FIFRA Good Laboratory Practice Regulations (48 FR 53946). Manufacturing-use products containing dicofol as the sole active ingredient may be registered or reregistered subject to the terms and conditions specified in this Guidance Document.

4. Registrants and applicants for registration must submit data regarding the composition of their product and in particular the concentration of DDTr contaminants in their manufacturing products. The Agency is concerned about the presence of these contaminants at levels substantially below one percent of the technical dicofol product because a no-effect-level has not been determined for reproductive effects in certain species of birds and because environmental modeling indicates that current usage may produce residues in fish that exceed the known effect for these reproductive effects (Balcomb, 1983b).

5. Because available residue data are inadequate and no definitive toxicity data are available, a tolerance reassessment cannot be performed at this time. A complete reassessment will be performed when the data specified in Tables A and B are supplied. There are also insufficient data to determine how much DDTr is contributed to the human diet when dicofol products are used. Special studies must be conducted to measure whether DDTr residues are present in or on food and feed crops and whether tolerances for DDTr are needed.

## D. REGULATORY RATIONALE

The following section provides the Agency's rationale to support the regulatory position described above.

### 1. Initiation of the Special Review

The Agency has concluded in its review of data during the reregistration process that dicofol, when used for certain outdoor applications, meet the risk criterion for unreasonable adverse effects (40 CFR 162.11(a)(3)(ii)(C)) because dicofol is contaminated with DDTr at levels which have unreasonable adverse effects on the environment. The risks of concern and the economic importance of pests controlled by dicofol products are summarized in the sections that follow. A Special Review will be initiated to examine the risks and benefits of these and other uses and to reach final regulatory conclusions.

Even though a Special Review will be initiated for dicofol, all current or prospective registrants of dicofol manufacturing-use products are still required to satisfy the requirements established by this Guidance Document. In particular, current registrants are responsible for generating and providing additional data required by the Guidance Document. Once the data being required by the Guidance Document have been submitted and reviewed, the Agency will determine whether those data warrant any changes in the Agency's current regulatory position.

### 2. Rationale and Procedures for Lowering DDTr Concentration

The risks of DDTr to the environment are well documented (see Section 4 A). The intention of the Special Review will be to reduce or eliminate these risks. One way to alleviate these risks is to reduce or eliminate the DDTr in the dicofol products. However, current manufacturing methods apparently preclude the production of dicofol without DDTr contamination. The Agency does not have adequate information to judge the level to which the registrants can feasibly reduce DDTr. Therefore, the Agency is requiring data on manufacturing methods, the levels of DDTr contamination in products, and updated Confidential Statements of Formula. It is the Agency's opinion that it would be prudent for registrants to modify their manufacturing processes to reduce the DDTr contamination to non-detectable levels in the technical product.

In order to develop a complete risk/benefit assessment evaluating dicofol use, the Agency will need data on the cost of altering the dicofol manufacturing process to reduce DDTr contamination. If registrants provide estimates of both capital costs and changes in operating costs necessitated to reduce DDTr in the manufacturing-use products, the Agency will consider this information in its final regulatory decision.

### 3. 1972 DDT Cancellation Order (37 FR 13369)

In 1972, the uses of nearly all pesticide products containing DDT and TDE were cancelled. However, products containing dicofol were not specifically mentioned under this Order. The Agency will evaluate the risks and benefits associated with each outdoor use of dicofol in the Special Review to determine whether revisions must be made to the terms and conditions of registration.

### 4. Preliminary Risk Assessment for DDTr Contaminants

#### a. Ecological Hazards Associated with DDT (Balcomb, 1983a)

Dicofol products contain DDT, DDD and DDE. It also contains a structurally similar chemical (Cl-DDT) of unknown toxicity that reportedly degrade to DDE. The Agency's assessment of the use of dicofol has considered risks that may result from the introduction of DDT, DDD, DDE and related compounds into the environment.

Historically, the use of DDT has adversely affected many terrestrial and aquatic organisms. DDE is of special concern because its long-term persistence and tendency to bioaccumulate in terrestrial and aquatic organisms allows for widespread exposure of wildlife. The use of DDT prior to

1972 resulted in mortality of certain species of birds, bats, fish and nontarget invertebrates. It has also had profound chronic effects in many animal species. Severe population reductions in birds and fish have been related to DDT's effects on reproduction.

Though dicofol outdoor uses are concentrated in certain regions of the United States, the resulting environmental contamination by DDTr may reach other areas. Because DDTr bioaccumulates in individual organisms and biomagnifies through some food chains (particularly those involving aquatic organisms), it is reasonable to assume that higher trophic level aquatic organisms and birds may be particularly impacted. Contamination, however, will not likely be confined only to use areas. One of the major reasons that virtually all uses of DDT were cancelled in 1972 is that its widespread use in the U.S. contributed to the nationwide DDTr burden. Elevated and possibly harmful DDE residues have recently been detected in wildlife in major dicofol use areas.

There is evidence that the level of DDT-related contamination, on a nationwide basis, is declining. Nonetheless, residues remain ubiquitous and may be high enough in some areas to affect bird and fish reproduction. Risk assessment for dicofol is therefore complicated in that its use in some areas may result in residues high enough to cause adverse effects, regardless of ambient concentrations, while other uses in other locations may incrementally increase ambient levels such that effects occur. It is not clear at this time that such distinctions can be made scientifically.

Because of the Agency's concerns that fish-eating birds may be exposed to residues of DDTr exceeding dietary levels known to impair reproduction, the Agency developed a model to estimate the level of DDTr residues in water (Hitch and Reinert, 1983). The simulation relies upon the Exposure Analysis Modeling System (EXAMS). The Arroyo Colorado waterway of southern Texas was chosen because of the high level of dicofol used on citrus and the important aquatic bird habitats in the drainage area. Under the conditions of steady-state chemical loading this model predicts the equilibrium concentration in a water body. The chemical input to the river system was estimated based on the following assumptions:

1) The amount of dicofol used each year in this drainage basin is 100,000 pounds. This is based on the estimate of 25,000 acres of citrus with drainage into the Arroyo Colorado, and the estimate that up to four pounds of dicofol active ingredient are used on citrus. Using this estimate, the highest label rate for a single application compensated for the legal use of multiple applications at less than the maximum rate.

2) For purposes of this simulation, the water in the river basin is assumed to be free of DDTr prior to the introduction of contaminated dicofol, which yields the EXAMS steady state concentration. Even though it is documented that background levels of DDTr occur ubiquitously throughout all matrices of the environment, this assumption is necessary to calculate the DDTr burden in fish that results solely from the use of dicofol.

3) The amount of DDTr added to the environment was arbitrarily factored in at 10% of the dicofol active ingredient applied. The model's residue predictions are a direct linear function of the loading so that aquatic residues for any level of product contamination can be estimated by proportionality.

4) The physical characteristics of DDT and DDE vary slightly and the modeling capabilities required the choice of one set of chemical parameters. From a calculation standpoint, counterbalancing factors mitigated the importance of choosing the physical properties of DDT or DDE for the purpose of aquatic fate modeling to predict the eventual concentration of DDE precursors in fish. For the EXAMS model, the physical parameters for p,p'-DDT, the most extensively studied analog, were used throughout the simulation and the environmental exposure assessment.

5) The Agency assumed that most of the DDTr reaching the Arroyo Colorado was transported by surface water running off the immediate drainage area in which dicofol had been used. A recent review of the available literature on pesticide runoff concluded that DDT consistently shows losses of 2 to 3% of the amount applied. Therefore, 2% of the DDT applied was assumed to reach the Arroyo Colorado as a consequence of surface water runoff.

Using the assumptions noted above, EXAMS predicted a steady state water column concentration of 9 parts per trillion (ppt) DDTr[2/]. Whole fish concentrations of 9 ppm DDTr were estimated to occur via bioaccumulation and biomagnification[3/]. Levels of DDTr contamination reported in the registrant's Confidential Stantement of Formula were then compared with the model's predictions. It was concluded that levels of reported DDTr contamination, if contained in dicofol products used in accordance with the model's assumptions, would generate DDTr residue levels in fish that would exceed dietary levels shown experimentally to reduce eggshell thickness. Effects on avian reproduction have been documented experimentally at dietary levels as low as 0.6 ppm DDE (wet weight). Monitoring studies of brown pelicans have indicated reproductive effects at lower dietary concentrations. Because all of the constituants of DDTr are known or

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2/ Significant uncertainty is necessarily associated with the type of quantitative exposure assessment presented. This uncertainty results from the difficulties in describing the geophysical environment, from incomplete physical-chemical parameters of the chemicals, and from an inability to completely describe with the EXAMS model the environmental processes that affect the transport and fate of the DDTr in this simulation. However, in the absence of monitoring data from a habitat receiving known loadings of DDTr, the use of a simulation model was considered to be the best available means of quantitatively estimating exposure to aquatic birds.

3/ Bioaccumulations of 1,000,000 have been determined in field studies.

expected to degrade to DDE, the Agency concludes that the residue levels of DDTr in fish pose a significant risk.

Caution must be used in extrapolating the values calculated for the Arroyo Colorado to other water basins due to the many location specific factors which can affect the magnitude of aquatic DDTr levels and the observed trends in the changes in environmental levels.

### b. Oncogenicity of Dicofol and DDT

The potential oncogenicity of dicofol per se is unknown due to the unavailablity of adequate studies. The data available do suggest possible oncogenicity in male mice. However, the study is unacceptable due to the reported decomposition of the test material during the study. Additional testing is required before a conclusion can be reached.

Laboratory tests have indicated that both DDT and DDE can cause tumors in mice. As indicated in the 1972 DDT cancellation decision, DDT should be considered a potential human carcinogen. However, adequate dietary exposure data are not available to estimate the potential risks to humans through dietary exposure to DDT contaminants in dicofol products. These data are being required from registrants, and when they are submitted, an assessment of the carcinogenic risk to humans will be made.

### 5. Groundwater Contamination

Dicofol residues are relatively immobile in soil. It does not leach below a depth of two inches in sandy loam soil, and in a soil runoff study, dicofol was found to be essentially immobile when incorporated into the top inch of a silt loam soil. Therefore, there is no expectation of groundwater contamination.

## 6. Current Benefits Review for Dicofol[4]

An estimated 2 million pounds of dicofol active ingredient are used annually as an acaracide in the United States (Devine, 1983; Luttner, 1981; Scheid, 1980). The major dicofol use sites are citrus and cotton[5]. These sites accounted for an estimated two-thirds of the dicofol usage during the 1980-1981 period.

The farm level value of U.S. orange, grapefruit, and lemon production was approximately $1.8 billion for the 1980-1981 citrus season. Dicofol is used throughout the citrus growing regions for control of spider mites. Spider mite nymphs and adults damage citrus foliage, limiting the trees' vigor and, therefore, ability to produce maximum yields of good marketable fruit. Other species of mites damage twigs and young limbs of citrus trees as well as damaging fruit and causing early fruit drop.

Uncontrolled mite populations reduce yield and quality of citrus and increase the average cost of citrus production. Although alternative acaricides to dicofol are available, dicofol's widespread use suggests that alternatives are less cost effective and/or preferable than dicofol for control of mite populations under specific circumstances.

The farm level value of U.S. cotton production is approximately $4 billion annually. Dicofol is used for spider mite control on cotton primarily in the state of California which produces approximately $1 billion of cotton annually. In general, the nymph and adult spider mites damage cotton foliage, stems, and fruit. Sustained, uncontrolled spider mite populations may build up and cause defoliation, bract desiccation, and shedding of cotton squares and bolls. Heavy feeding can cause reduced lint quality and yield, as well as, lowered cotton seed production and viability.

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[4] More detailed information on dicofol use, usage, and economic benefits can be found in two Agency documents prepared under the registration standards process. Sutherland and Gross, 1983, dicusses the biological aspects of dicofol use. Vlier, 1983, presents a preliminary review of the economic benefits of dicofol use on cotton and citrus.

[5] Most dicofol use on cotton occurs in the San Joaquin Valley.

Uncontrolled mite populations would therefore increase the average unit cost of cotton. As in the case of citrus, although alternative acaricides to dicofol are available, dicofol's use, particularly in the the San Joaquin Valley, suggests that alternatives are less cost effective and/or less preferable than dicofol for control of mite populations under specific circumstances.

## E. CRITERIA FOR PRODUCTS SUBJECT TO THIS GUIDANCE DOCUMENT

To be covered by this Guidance Document, products must contain dicofol as the sole active ingredient, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in Section F of this Document.

The applicant for registration or reregistration of products subject to this Document must comply with all terms and conditions described herein. These include making a commitment to fill data gaps on a schedule specified by the Agency. Also, applicants for registration under this Document must contact the Agency for specific instructions, including updated information on data requirements and companies whose data satisfy the Agency's data requirements. Applicants for registration or reregistration must follow the instructions contained in this Guidance Document and complete and submit the appropriate forms within the time specified.

## F. ACCEPTABLE RANGES AND LIMITS

### 1. Product Composition Standard

To be fully covered under this Guidance Document, manufacturing-use products must contain dicofol as the sole active ingredient. Each manufacturing-use product formulation proposed for registration or re-registration must be fully described and an appropriate certification of limits must be included. The label must also state the nominal concentration for the active ingredient. However, because the Agency is concerned about DDT and related compounds as impurities in the manufacturing-use product, quantification of these impurities must be at a level of detection below 0.1% of the manufacturing-use product using the best suitable analytical methods (preferably gas liquid chromatography or high pressure liquid chromotography). The registrant must identify the analytical methods use.

### 2. Acute Toxicity Limits

The Agency will consider for registration any manufacturing-use product whose any acute toxicity category is supported by adequate acute toxicology data and labeling, including appropriate precautionary statements.

### 3. Use Patterns

To be covered under this Guidance Document, manufacturing-use products must be labeled for formulation into end-use products which are registered by the U.S. Environmental Protection Agency.

## G. REQUIRED LABELING

All dicofol products must bear appropriate labeling as specified in 40 CFR 162.10. Because of the absence of data required to assess the environmental and health hazards of dicofol, the Agency is not able to evaluate the adequacy of all precautionary and required statements on manufacturing-use product labels. This Guidance Document does not require changes in the current precautionary statements and environmental hazard labeling. The Agency may, after review of data to be submitted in response to this Document, require additional revisions to current labels, and may impose additional label requirements.

All manufacturing-use product labels must bear the following statement:

"For Formulation into End-Use Products Intended Only for Uses Accepted by the U.S. Environmental Protection Agency."

## H. TOLERANCE REASSESSMENT

U.S. tolerances are established for residues of dicofol in or on raw agricultural products as follows (40 CFR 180.163):

30 ppm in or on hops;

25 ppm in or on peppermint hay and spearmint hay;

10 ppm in or on apricots, grapefruit, kumquats, lemons, limes, nectarines, oranges, peaches, tangerines;

5 ppm in or on apples, beans (dry), snap beans (succulent), lima beans (succulent), blackberries, boysenberries, bushnuts, butternuts, cantaloupes, cherries, chestnuts, crabapples, cucumbers, dewberries, eggplant, figs, filberts, grapes, hazelnuts, hickory nuts, loganberries, melons, muskmelons, pears, pecans, peppers, pimentos, plums (fresh plums), pumpkins, quince, raspberries, summer squash, strawberries, tomatoes, walnuts, watermelons, winter squash;

0.1 ppm in or on cottonseed.

Tolerances for dicofol commodities may be expressed as residues of dicofol and its metabolites. Some of the metabolites have yet to be identified. Therefore, following their identification, all existing tolerances for dicofol must be reassessed. If the requested additional residue data indicate the presence of residues of DDTr in or on raw agricultural commodities resulting from the the registered uses of dicofol on these raw agricultural commodities, then residue tolerances for DDTr for these commodities may be required.

Current labels allow for maximum application rates greater than those established with the above tolerances. Thus, current tolerances do not reflect the current use rates, with the exception of mint and strawberries.

Further, there are no established tolerances for dicofol residues on currants, gooseberries, peanuts, field corn and sugar beets (roots and tops). All of the dicofol products used on these commodities are intrastate products, that is they were registered State labels. In addition, the following commodities, which appear on labels of federally registered dicofol products, have no tolerance: almonds, caneberries, olallieberries, potatoes, prunes, and tangelos. Residue data described in Table A of this Document must be generated for these commodities, and petitions for tolerances must be submitted.

Processing studies will be required to show the amount of residues in the following processed commodities: apple pomace, tomato pomace, tomato waste, citrus pulp, citrus oil, grape pomace, raisin waste, cottonseed by-products (i.e. cottonseed meal and hulls, cottonseed oil).

If the processing causes residues to concentrate at levels that would exceed the tolerance established for the raw agricultural commodity, a food additive tolerance for the by-product will be required.

Animal feeding studies with large ruminants and poultry are required to establish the extent of transfer or residues to meat, milk, poultry, and eggs.

Two uses, for alfalfa and clover seed crops, are designated as food uses of dicofol and require tolerances under the Federal Food, Drug, and Cosmetic Act.

The Theoretical Maximum Residue Contribution (TMRC) is 1.607 mg/day as dicofol, assuming a 1.5 kg diet, based on the tolerances and food factors for all commodities for which U.S. tolerances are established. A report by the Food and Drug Administration's Regulatory Enforcement Program shows that residues of dicofol found on many agricultural crops during FY 1976, 1977, 1978, 1979, and 1980 did not exceed the residue tolerances for these crops.

No Acceptable Daily Intake (ADI) or Maximum Permissible Intake (MPI) figures have been established, due to the absence of acceptable toxicological data for dicofol. The ADI will be established when appropriate testing data are available. Until all required data have been submitted and reviewed, the current U.S. tolerances for dicofol will remain in effect.

## I. SPECIAL STUDIES

The following special studies are required to resolve the questions regarding the environmental fate, effects, and product chemistry of DDTr compounds.

### 1. Environmental Fate

Environmental fate studies utilizing Cl-DDT as the test substance will be required to support the registration of all manufacturing-use products containing this compound. These environmental fate studies shall include all tests cited in Table A (Generic Data Requirements for Dicofol), except for the crop rotation tests. (Note: The tendency of Cl-DDT to accumulate in rotational crops will be evaluated in the appropriate studies with dicofol technical). Additionally, it is noted that the aerobic and anaerobic aquatic metabolism and aquatic field dissipation studies listed in §158.130 are needed because of a significant potential for transport to water has been demonstrated.

Protocols for these studies must be submitted to the Agency within three months of the receipt of this Guidance Document by registrants. These studies must be designed so as to clearly indicate the chemical fate of Cl-DDT in the environment. The Agency recognizes that certain impurities must necessarily occur in any sample of Cl-DDT which the registrant might select as a test substance. The protocols utilized by the registrant must, therefore, clearly indicate how the degradation products of Cl-DDT can be distinguished from the impurities and their derivatives.

## 2. Ecological Effects

No effects data are available for Cl-DDT, therefore chronic toxicity studies with birds, fish, and aquatic invertebrates are required (Data Requirements Table A).

Estimated environmental residues of DDTr (from the EXAMS model) are within the range of concentration showns to cause effects in monitoring and experimental studies with DDTr. If registrants are able to substantially reduce the DDTr in dicofol to levels that would indicate environmental exposures below that for which the Agency can predict effects with the existing data base (no-effect levels are not yet known), extensive ecological effects testing would be required to overturn the Agency's presumption that such low levels may be harmful.

Field monitoring which would disprove a possible linkage between dicofol use and environmental effects of DDTr such as, for example, eggshell thinning or impairment of fish reproduction, may be impossible or too impractical to conduct. Factors such as ambient DDTr contamination, differential species sensitivity, latency of effects, chemical persistance and mobility, and the varied biological and physical make-up of potential use sites, which all must be taken into consideration in a general proof may confound such studies or require that they be unreasonably complex.

### 3. Product Chemistry

Registrants certifying the presence of Cl-DDT in their manufacturing-use products are required to submit measurements of the octanol-water partition coefficient ($K_{OW}$), water solubility, and vapor pressure for this chemical.

## II. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

A. This portion of the guidance document is a Notice issued under the authority of FIFRA Section 3(c)(2)(B) and describes, in table format, the data required for maintaining the registrability of each product. Additionally, a bibliography (Appendix II-1) is included that identifies that data considered as part of the data base supporting this standard. EPA has determined that additional generic data described in this Notice must be submitted to EPA for evaluation in order to maintain in effect the registration(s) of your product(s) identified as an attachment to the cover letter accompanying this guidance document. As required by FIFRA Section 3(c)(2)(B), you are required to take appropriate steps to comply with this Notice.

EPA may suspend the registration of each of those products unless, within the specified time, you have informed EPA how you will satisfy the requirements of this Notice. Any such suspension will remain in effect until you have complied with the terms of this Notice.

B. What Generic Data [1] Must Be Submitted. You may ascertain which generic data you must submit by consulting Table A at the end of this chapter. That table shows all the generic data needed to evaluate the continued registrability of all products, and the dates by which the data must be submitted. The required data must be submitted 2/. Any necessary studies must be conducted in accordance with EPA-approved protocols, the Pesticide Registration Guidelines 3/, or data collected under the approved protocols of the Organization for Economic Cooperation and Development (OECD). If you wish not to develop data which are necessary to support the registration or reregistration of certain uses appearing in your labeling, you may delete those uses at the time you submit your revised labeling.

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1/ Generic data pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition or use. Produc-specific data relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition).

2/ USEPA, 1982. Pesticide Registration; Proposed Data Requirements - Part 158. FEDERAL REGISTER of November 24, 1982 (47 FR 53192)

3/ USEPA, 1983. Pesticide Assessment Guidelines, National Technical Information Service, Springfield, VA.

Also for certain kinds of testing (generally ecological effects), EPA requires the test substance to be a "typical formulation," and in those cases EPA needs data of that type for each major formulation category (e.g., emulsifiable concentrates, wettable powders, granulars, etc.) These are classified as generic data and when needed are specified in Table A. EPA may possess data on certain "typical formulations" but not others. Note: The "typical formulation" data should not be confused with product-specific data (Table B) which are required on each formulation. Product-specific data are further explained in Chapter IV of this document.

## C. Options Available for Complying With Requirements to Submit Data

Within 90 days of your receipt of this Notice you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" [EPA Form 8580-1, Appendix II-2] for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice:

1. (a) Notify EPA that you will submit the data, and

   (b) either submit the existing data you believe will satisfy the requirement, or state that you will generate the data by conducting testing. If the test procedures you will use deviate from (or are not specified in) the Registration Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must enclose the protocols you will use.

2. Notify EPA that you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option, you must notify EPA which registrant(s) are parties to the agreement.

3. File with EPA a completed "Certification of Attempt to Enter Into an Agreement With Other Registrants for Development of Data" (EPA Form 8580-6, Appendix II-3)*/

4. Request that EPA amend your registration by deleting the uses for which the data are needed. (This option is not available to applicants for new products.)

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*/ FIFRA Section 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree (Footnote continued at bottom of next page)

5. Request voluntary cancellation of the registration(s) of your products for which the data are needed. (This option is not available to applicants for new products.)

## D. Procedures for Requesting Changes in Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with our conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted. If the test procedures you plan to use deviate from (or are not specified in) the registration guidelines or protocols contained in the reports of the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit the protocol for Agency review prior to the initiation of the test.

If you think that you will need more time to generate the required data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager. The extension request should state the reasons why you conclude that an extension is appropriate. While EPA considers your request, you must strive to meet the deadline for submitting the required data.

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(Footnote continued from previous page) to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.

In EPA's opinion, joint data development by all registrants who are subject to the requirements to submit a pertinent item of data or a cost-sharing agreement among all such registrants is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing.

As noted earlier, EPA has discretion not to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it is appropriate to exercise its discretion not to suspend in ways which will discourage duplicative testing. Accordingly, if (1) a registrant has informed us of his intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii)]; and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration. While the first firm is not required to agree to jointly develop data, EPA is not required to force the second firm to engage in economically inefficient duplicative testing in order to maintain its registration.

## III. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Note: This chapter applies only to manufacturing-use products, not end-use products.

A necessary first step in determining which statements must appear on your product's label is the completion and submission to EPA of product-specific data* listed on the form entitled "Product Specific Data Report" (EPA Form 8580-4, Appendix III-1) to fill "gaps" identified by EPA concerning your product. Under the authority of FIFRA Section 3(c)(2)(B), EPA has determined that you must submit these data to EPA in order to register or reregister your product(s). All of these data must be submitted not later than six months after you receive this guidance document.

"Product-Specific Data Requirements for Manufacturing-Use Products" appearing in Table B permit you to determine which product-specific data you must submit. This can be done by examining the entries in the column of those tables entitled "Must Data Be Submitted Under §3(c)(2)(B)."

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*/ Product specific data pertains to data that support the formulation which is marketed; it usually includes product chemistry data and acute toxicology data.

## TABLE A
## GENERIC DATA REQUIREMENTS FOR DICOFOL

| Data Requirement | Composition 1/ | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/ |
|---|---|---|---|---|
| **§158.120 Product Chemistry** | | | | |
| **Product Identity:** | | | | |
| 61-1 - Identity of Ingredients | TGAI | No | - | Yes 3/ |
| 61-2 - Statement of Composition | TGAI | No | - | Yes 3/ |
| 61-3 - Discussion of Formation of Impurities | TGAI | Partially | Confidential Statement of Formula | Yes 4/ |
| **Analysis and Certification of Product Ingredients** | | | | |
| 62-1 - Preliminary Analysis | TGAI | No | | Yes 5/ |
| 62-2 - Certification of Limits | TGAI | Partially | Confidential Statement of Formula | Yes 6/ |
| 62-3 - Analytical Methods for Enforcement of Limits | | | | |
| - Active Ingredient | MP | Yes | 05005142, 00004348 a/<br>05014643, 05017499<br>00004340, 05004951<br>05005964, 05006333<br>05005167, 00004336 b/<br>05015278, 05020221<br>05005274, 05004878<br>05005279, 05015625<br>05017892 | No |

## TABLE A
## GENERIC DATA REQUIREMENTS FOR DICOFOL

| Data Requirement | Composition[1] | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2] |
|---|---|---|---|---|
| §158.120 Product Chemistry | | | | |
| - Impurities | MP | Yes | 05004176 | No |
| Physical and Chemical Characteristics | | | | |
| 63-2 - Color | TGAI | Yes | 00004358[c], 00004339[d] | No[7] |
| 63-3 - Physical State | TGAI | Yes | 00004358[c], 00004339[d] | No |
| 63-4 - Odor | TGAI | No | - | Yes |
| 63-5 - Melting Point | TGAI | Yes | 00004358[c], 00004339[d] | No[7] |
| 63-6 - Boiling Point | TGAI | No | - | Yes |
| 63-7 - Density, Bulk Density, or Specific Gravity | TGAI | Yes | 00004358, 00004339 | No |
| 63-8 - Solubility | TGAI or PAI | Partially | 00004358[c], 00004339[d] | Yes[8] |
| 63-9 - Vapor Pressure | PAI | No | - | Yes |
| 63-10 - Dissociation constant | PAI | No | - | Yes |
| 63-11 - Octanol/water partition coefficient | PAI | No | - | Yes |
| 63-12 - pH | TGAI | No | - | No |
| 63-13 - Stability | TGAI | No | - | Yes |
| Other Requirements: | | | | |
| 64- 1 - Submittal of samples | Choice | No | - | Yes |

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = Pure active ingredient; Choice = Choice of several test substances determined on a case-by-case basis.
2/ Data must be submitted no later than April, 1984.
3/ Updated information must be supplied by all companies on identity and quantity of impurities and inert ingredients. Special attention must be given to identifying and quantifying the DDT impurities. The name and address of the producer of the starting materials, the manufacturing process, and the reaction conditions are needed.
4/ Special testing is required on the impurity known as Cl-DDT. These tests are the octanol-water partition coefficient, water solubility, and vapor pressure.
5/ Five or more representative samples should be analyzed for the amount of active ingredient and each impurity present in the technical material for which a certified limit is required.
6/ Upper and lower limits must be provided and certified for the dicofol concentrations and each impurity > 0.1 percent.
7/ Aceto Chemical did not submit any physical/chemical properties. Rohm & Hass and Makhteshim Beer-Shiva did report some of these properties for their technical products.
8/ Solubility should be expressed in grams/100 ml solvent or ppm at 20°C.
9/ Not soluble in water.

a/ Data submitted by Intrachem, S.A. These data may be compensable.
b/ Data submitted by Aceto Chemical Company. These data may be compensable.
c/ Data submitted by Rohm and Haas Company. These data may be compensable.
d/ Data submitted by Makhteshim Beer-Sheva Chemical Works, Limited. These data may be compensable.

## TABLE A
## GENERIC DATA REQUIREMENTS FOR DICOFOL

| Data Requirements | Composition [1/] | Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? [2/] |
|---|---|---|---|---|
| §158.125 Residue Chemistry | | | | |
| 171-4 - Nature of Residue (Metabolism) | | | | |
| - Plants | PAIRA | Partially | 05000993, 05006528<br>00004275, 00004321<br>05004877, 05006219 | Yes [3/] |
| - Livestock | PAIRA and plant metabolites | No | | Yes |
| 171-4 - Residue Analytical Method | | | | |
| - Plant residues | TGAI and metabolites | Partially | 05005274, 00004420<br>05005165, 00004341[a/]<br>05005167, 05004945<br>05004951, 05005141<br>05006330, 00004371<br>00004426, 05017942<br>05005537, 05006312<br>05012262, 05019781 | Yes [4/] |
| - Animal residues | TGAI and metabolites | No | | Yes |
| 171-4 - Storage Stability Data | PAI | No | - | Yes |
| 171-4 - Magnitude of the Residue-Residue Studies for Each Food Use | | | | |
| Peppermint Hay | TEP | Yes | 00004324, 00004323<br>00021700, 00021701<br>00004272, 00004322 | No |

## TABLE A
## GENERIC DATA REQUIREMENTS FOR DICOFOL

| Data Requirements | Composition [1] | Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? [2] |
|---|---|---|---|---|
| **§158.125 Residue Chemistry** | | | | |
| Mint Oil | TEP | Yes | 00004321, 00021701 | No |
| Spearmint Hay | TEP | Yes | 00004324, 00021700<br>00004272 | No |
| Strawberries | TEP | Yes | 00004305 | No |
| Hops | | Partially | 00004305 | Yes [5] |
| Apricots, nectarines, peaches | | Partially | 00004305 | Yes [5] |
| Grapefruit, kumquats, lemons, oranges, tangerines | | Partially | 00004305 | Yes [5] |
| 171-4 - Magnitude of the Residue - Residue studies for each food use | | | | |
| Apples, crabapples, pears, quinces | | Partially | 00004504 | Yes |
| Blackberries, boysenberries, dewberries, loganberries, raspberries | | Partially | 00004305 | Yes [5] |
| Cherries, plums, prunes | | Partially | 00004305 | Yes [5] |
| Beans (dry) | | Partially | 00004305 | Yes [5] |

## TABLE A
## GENERIC DATA REQUIREMENTS FOR DICOFOL

| Data Requirements | Composition[1] | Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2] |
|---|---|---|---|---|
| §158.125 Residue Chemistry (continued) | | | | |
| Snap beans, lima beans (succulent form) | | Partially | 00004305, 00019894 | Yes[5] |
| Cantaloupes, melons, muskmelons, pumpkins, watermelons, winter squash | | Partially | 00004305 | Yes[5] |
| Cucumbers and summer squash | | Partially | 00004305 | Yes[5] |
| Bushnuts, butternuts, chestnuts hazelnuts, hickorynuts, pecans, walnuts, filberts | | Partially | 00004305 | Yes[5] |
| Tomatoes, eggplants, peppers, pimentos | | Partially | 00004305 | Yes[5] |
| Grapes, figs | | Partially | 00004305 | Yes[5] |
| Cottonseed | | Partially | 00004305 | Yes[5] |
| Field corn | | No | | Yes |
| Alfalfa and clover | | No | | Yes |
| Potable water | TEP | No | | Yes |
| Fish | TEP | - | - | No |
| Irrigated crops | TEP | - | - | No |
| Food Handling | TEP | - | - | No |

## TABLE A
## GENERIC DATA REQUIREMENTS FOR DICOFOL

| Data Requirements | Composition 1/ | Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/ |
|---|---|---|---|---|
| §158.125 Residue Chemistry (continued) | | | | |
| 171-4 - Magnitude of the Residue - Residue studies for each food use | | | | |
| Residue studies in food-producing animals | | | | |
| - Meat | TEP | Partially | 05004708 | Yes 6/ |
| - Milk | TEP | No | - | Yes |
| - Poultry | TEP | Partially | 05026372, 05005377 | Yes 6/ |
| - Eggs | TEP | No | - | Yes |

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1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product; EP = End-use product.

2/ Data must be submitted no later than December, 1986.

3/ It has been concluded by the Agency that the metabolic fate of dicofol in or on plants has not been adequately demonstrated. Further testing will be required using $C^{14}$dicofol to identify the metabolites and/or degradation products in the final residue.

4/ Since there is no adequate profile of the fate of dicofol residues in or on plants and animals, no opinion can be offered about whether or not there are adequate methods to collect the residue data and to enforce the established tolerances. When they are revised, the dicofol tolerances may have to be expressed in terms of residues of dicofol and its metabolits, or degradation products. Methods in that case will have to be available to determine the metabolites, or degradation products.

5/ Although for most crops residue data were submitted, due to the changes of application rates and pre-harvest intervals, these outdated data are not adequate to support the registered uses under present day standards, and the established tolerances are not supported.

6/ It is the Agency's opinion that proper feeding studies with large ruminants and poultry should be performed, indicating at what feeding level residues start to appear in meat, milk, poultry and eggs.

a/ Data submitted by Makhteshim Beer-Sheva Chemical Works, Limited. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR DICOFOL

| Data Requirement | Composition [1] | Use Pattern [2] | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? [3] |
|---|---|---|---|---|---|
| §158.130 Environmental Fate | | | | | |
| DEGRADATION STUDIES-LAB: | | | | | |
| 161-1 - Hydrolysis | TGAI or PAIRA | A,B,E,F,H | Partially | GS021003[a] | Yes[4] |
| Photodegradation | | | | | |
| 161-2 - In water | TGAI or PAIRA | A,B | No | GS021005[a] | Yes[5] |
| 161-3 - On soil | TGAI or PAIRA | A | No | - | Yes |
| 161-4 - In Air | TGAI or PAIRA | A | No | - | Yes |
| METABOLISM STUDIES-LAB: | | | | | |
| 162-1 - Aerobic Soil | TGAI or PAIRA | A,B,E,F,H | Partially | GS021001[a], GS021004[a] | Yes[6] |
| 162-2 - Anaerobic Soil | TGAI or PAIRA | A | No | - | Yes |
| 162-3 - Anaerobic Aquatic | - | - | - | - | No[7] |
| 162-4 - Aerobic Aquatic | - | - | - | - | No[7] |
| MOBILITY STUDIES: | | | | | |
| 163-1 - Leaching and Adsorption/Desorption | TGAI or PAIRA | A,B,E,F,H | Yes | GS021002[a], GS021007[a] | No |
| 163-2 - Volatility (Lab) | TEP | A,E,F | Yes | 05011076 | No |
| 163-3 - Volatility (Field) | TEP | A,E,F | No | - | Yes |

## TABLE A
## GENERIC DATA REQUIREMENTS FOR DICOFOL

| Data Requirement | Composition 1/ | Use Pattern 2/ | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/ |
|---|---|---|---|---|---|
| §158.130 Environmental Fate | | | | | |
| DISSIPATION STUDIES-FIELD: | | | | | |
| 164-1 - Soil | TEP | A,B,H | Partially | GS021008 a/, GS021004 a/ | Yes 8/ |
| 164-2 - Aquatic (sediment) | - | - | - | - | No 7/ |
| 164-3 - Forestry | - | - | - | - | No 9/ |
| 164-4 - Combination and Tank Mixes | - | - | - | - | No 10/ |
| 164-5 - Soil, Long-term | TEP | A | Partially | GS021008 a/, GS021004 a/ | Yes 11/ |
| ACCUMULATION STUDIES: | | | | | |
| 165-1 - Rotational Crops (Confined) | PAIRA | A | Partially | 05012142, GS021013 a/ | Yes 12/ |
| 165-2 - Rotational Crops (Field) | TEP | A | No | - | Yes |
| 165-3 - Irrigated Crops | - | - | - | - | No 13/ |
| 165-4 - In Fish | TGAI or PAIRA | A,B | Partially | GS021013 a/ | Yes 14/ |
| 165-5 - In Aquatic Nontarget Organisms | TGAI or PAIRA | A,B | No | - | Yes |

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product.

2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aqautic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

3/ Data must be submitted no later than December, 1986.

4/ The study partially satisfies the data requirement for hydrolysis by providing information on the rate of hydrolysis of dicofol in buffered solutions at one concentration, one temperature, and three pHs (acidic, neutral, and basic). A material balance and identification of all degradation products greater than 10% of the initial dicofol concentration could not be determined. One additional study at a different concentration and temperature at acidic, neutral, and basic pHs is required. The study should include a material balance and the identification of all degradation products greater than 10% of the initial dicofol concentration.

5/ The photolysis study was conducted on silica gel-coated thin layer plates, which is no longer a data requirement. For the use patterns identified for dicofol, photodegradation studies are required to be conducted in distilled or deionized water, on soil, and in air.

6/ Sufficient data on dicofol aerobic soil metabolism in silt loam are available, which is one of the three soil types required. Two additional soil types must be tested, one should be a sandy loam and the other should be appropriate to the intended use areas.

7/ There are no registered aquatic uses for dicofol.

8/ Field dissipation studies are required to be conducted under actual use conditions, using the representative formulated product. However, the submitted studies were conducted using $^{14}C$-dicofol formulated into an emulsifiable concentrate. Since the results of the studies provided data on the material balance, in addition to data on persistence, mobility, and identification of degradation products, the Agency will accept the studies as satisfying the data requirement for silt loam, which is one of the four soil types required. Three additional field dissipation studies are required using soil types appropriate to the intended use areas. One of the three types of soil should be sandy loam.

9/ There are no registered forestry uses for dicofol.

10/ This Guidance Document deals only with single active ingredients.

11/ Long term field dissipation studies are required to be conducted under actual use conditions, using the representative formulated product. However, the submitted studies were conducted using $^{14}C$-dicofol formulated into an emulsifiable concentrate. Since the results of the studies provided data on the material balance, in addition to data on persistence, mobility, and identification of degradation products, the Agency will accept the studies as satisfying the data requirement for silt loam, which is one of the four soil types required. Three additional field dissipation studies are required using soil types appropriate to the intended use areas. One of the three types of soil should be sandy loam.

(footnotes continued on next page)

12/ Results of the submitted rotational crop study indicated that there is a potential for dicofol and its residues to accumulate in rotational crops. However, the sampling intervals in the confined rotational crop studies were inappropriate to assess the potential uptake of dicofol and its residues at 30 days, four months, and one year after the last dicofol application. Therefore, an additional confined rotational crop study with the appropriate sampling interals is required. This study should be conducted using the manufacturing-use product as the test substance. The analytical method utilized in the study must be capable of separating and measuring dicofol, its residues, and its impurities (DDTr) in the confined rotational crops. Alternatives to conducting the confined rotational crop study are: 1) rotational crop studies conducted under actual use conditions, 2) a label restriction that prohibits crop rotation with crops other than those specified on the label, or 3) a tolerance for the nontarget crop.

13/ Dicofol is not registered for intentional application to irrigation water.

14/ The protocol for the submitted ecosystem study is inappropriate to assess the potential accumulation of dicofol and its residues in fish, because the exposure period was not long enough, nor was there a depuration period included in the protocol to assess elimination of dicofol and its residues from fish. A flowthrough system fish accumulation study is required. This study should be conducted using the manufacturing-use product as the test substance. The identity of the test substance should be specified (qualitative and quantitative description of the chemical composition). The analytical method utilized in the study must be capable of separating and measuring the DDT* impurities in the test substance.

a/ Data submitted by Rohm and Haas Company. These data may be compensable.

## TABLE A
## GENERIC DATA REQUIREMENTS FOR DICOFOL

| Data Requirement | Composition [1] | Use Patterns [2] | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Data Be Submitted Under FIFRA Section 3(c)(2)(B)? |
|---|---|---|---|---|---|
| §158.135 Toxicology | | | | | |
| ACUTE TESTING: | | | | | |
| 81-1 - Oral $LD_{50}$ - Rat | TGAI | A,B,E,F,H,I | Yes | 00004373, 00004365<br>05002571, 00004374 | No |
| 81-2 - Dermal $LD_{50}$ | TGAI | A,B,E,F,H,I | Yes | 00004366 | No |
| 81-3 - Inhalation $LC_{50}$ - Rat | TGAI | A,B,E,F,H,I | No | - | Yes |
| 81-7 - Acute Delayed Neurotoxicity - Hen | - | - | - | - | No [4] |
| SUBCHRONIC TESTING: | | | | | |
| 82-1 - 90-Day Feeding - Rodent, Non-rodent | TGAI | A,B,E,F,H,I | Partially | 00004429 | Yes [5] |
| 82-2 - 21-Day Dermal | TGAI | A,B,E,F,H,I | No | - | Yes |
| 82-3 - 90-Day Dermal | TGAI | - | No | - | No [6] |
| 82-4 - 90-Day Inhalation - Rat | TGAI | A,B,E,F,H,I | No | - | Reserved [7] |
| 82-5 - 90-Day Neurotoxicity- Hen/Mammal | - | - | No | - | No [4] |

TABLE A
GENERIC DATA REQUIREMENTS FOR DICOFOL

| Data Requirement | Composition[1] | Use Pattern[2] | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)? | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3] |
|---|---|---|---|---|---|
| CHRONIC TESTING: | | | | | |
| 83-1 - Chronic Toxicity - 2 species: Rodent and Non-rodent | TGAI | A,B,E,F,H,I | No | - | Yes |
| 83-2 - Oncogenicity Study - 2 species: Rat and Mouse preferred | TGAI | A,B,E,F,H,I | No | GS021051 | Yes[8] |
| 83-3 - Teratogenicity - 2 species | TGAI | A,B,E,F,H,I | No | - | Yes |
| 83-4 - Reproduction, 2-generation | TGAI | A,B,E,F,H,I | Yes | 00004424, 00004312 | No |
| §158.135 Toxicology (continued) | | | | | |
| MUTAGENICITY TESTING | | | | | |
| 84-2 - Gene Mutation | TGAI | A,B,E,F,H,I | No | - | Yes[9] |
| 84-2 - Chromosomal Aberration | TGAI | A,B,E,F,H,I | No | - | Yes[9] |
| 84-2 - Other Mechanisms of Mutagenicity | TGAI | A,B,E,F,H,I | No | - | Yes[9] |
| SPECIAL TESTING | | | | | |
| 85-1 - General Metabolism | PAI or PAIRA | A,B,E,F,H,I | No | 05002571 | Yes[10] |
| 85-2 - Domestic Animal Safety | Choice | - | - | - | No |

1/ Composition: TGAI = Technical grade of the active ingredient. PAIRA = Pure active ingredient, radiolabelled; Choice = Choice of several test substances determined on a case-by-case basis. Due to the uncertainties of the dicofol impurities (DDTr), and their contribution, if any to a possible risk potential, all TGAI dicofol must be similar in composition. Any variation of the levels of impurities may result in additional toxicology data testing and requirement The Agency shall make data testing decisions on a case-by-case basis for each submitted statement of formula.

2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aqautic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

3/ Data must be submitted no later than December, 1986.

4/ This test is not required because dicofol does not depress cholinesterase acivity, and it is not structurally related to a compound that induces neuropathy or delayed neurotoxicity.

5/ The rat study submitted was adequate, testing in a second species, preferably the dog, is required.

6/ This test is not required because dicofol in not intentionally applied to the skin and its use will not result human exposure similar to that caused by swimming pool additives or pesticide-impregnated fabrics.

7/ 90-day inhalation toxicity testing requirement is reserved pending results from the acute inhalation test.

8/ The data available on oncogenicity do suggest possible oncogenicity in male mice. However, the study is unacceptable due to the reported decomposition of the test material during the study.

9/ The minimum standard for mutagenicity testing is: 1) Two different tests that are sensitive for point mutations, one for a mammalian system (in vivo or in vitro), 2) Two tests for chromosomal damage, and 3) one auxillary test for DNA damage on a test appropriate for other mechanisms of toxicity, i.e. DNA repair, induct test.

10/ A metabolism study comparing DDT and dicofol in the rat was started but not completed (various tissues removed for examination were not identified and assays were not reported, identification of purity and/or contaminants in the test substance were not reported). A request for a final report was made, however the registrant replied that the study was never completed.

TABLE A
GENERIC DATA REQUIREMENTS FOR DICOFOL

| Data Requirement | Composition[1] | Use Pattern[2] | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3] |
|---|---|---|---|---|---|
| §158.145 Wildlife and Aquatic Organisms | | | | | |
| AVIAN AND MAMMALIAN TESTING | | | | | |
| 71-1 - Avian Oral $LD_{50}$ | TGAI | A,B,H | Yes | 00004315, 00004314 | No |
| 71-2 - Avian Dietary $LC_{50}$ | TGAI | A,B,H | Yes | GS021052 | No |
| 71-3 - Wild Mammal Toxicity | - | - | - | - | No[4] |
| 71-4 - Avian Reproduction | TGAI | A,B,H | Partially | GS021014 | Yes[5] |
| 71-5 - Simulated and Actual Field Testing - Mammals and Birds | TEP | A,B,H | No | - | No[4] |
| AQUATIC ORGANISM TESTING | | | | | |
| 72-1 - Freshwater Fish $LC_{50}$ | TGAI | A,B,H | Partially | GS021048, GS021049 | Yes |
| 72-2 - Acute $LC_{50}$ Freshwater Invertebrates | TGAI | A,B,H | Partially | GS021060 | Yes[7] |
| 72-3 - Acute $LC_{50}$ Estuarine and Marine Organisms | TGAI | A,B,H | Partially | GS021063, GS021046<br>GS021047<br>05005326 | Yes[8] |
| 72-4 - Fish Early Life Stage and Aquatic Invertebrate Life-Cycle | TGAI | A,B,H | Yes | GS021062 | No |
| 72-5 - Fish Life-Cycle | TGAI | A,B,H | No | - | Yes |

## TABLE A
## GENERIC DATA REQUIREMENTS FOR DICOFOL

| Data Requirement | Composition 1/ | Use Pattern 2/ | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/ |
|---|---|---|---|---|---|
| §158.145 Wildlife and Aquatic Organisms | | | | | |
| AQUATIC ORGANISM TESTING | | | | | |
| 72-6 - Aquatic Organism Accumulation | TGAI, PAI or Degradation Product | A,B,H | No | - | Yes |
| 72-7 - Simulated or Actual Field Testing - Aquatic Organisms | TEP | - | No | - | No 9/ |
| §158.140 Reentry Protection | | | | | |
| 132-1 - Foliar Dissipation | TEP | - | - | - | Reserved 4/ |
| 132-1 - Soil Dissipation | TEP | - | - | - | Reserved 4/ |
| 133-3 - Dermal Exposure | TEP | - | - | - | Reserved 4/ |
| 133-4 - Inhalation Exposure | TEP | - | - | - | Reserved 4/ |

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1/ Composition: TEP = Typical end-use product.

2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

3/ Data must be submitted no later than December, 1986.

4/ These tests are reserved pending the receipt of additional data (inhalation, chronic feeding, oncogenicity, and teratogenicity).

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = pure active ingredient; TEP = Typical end-use product;

2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food Crop; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

3/ Data must be submitted no later than December, 1986.

4/ This test is required only on a case-by-case basis when hazards to nontarget vertebrates are likely. Lowered tiered testing does not indicate a potential hazard to nontarget vertebrates.

5/ The avian reproduction requirement involves testing with two species (mallard and bobwhite). Testing with mallards has been received but it does not fulfill the requirements; mallard and bobwhite testing are required.

6/ Testing is required on a coldwater fish species.

7/ There are insufficient data available in the submitted study to permit a statistical validation.

8/ Dose mortality data are not provided in the original citation.

9/ This test is required on a case-by-case basis when hazards to nontarget aquatic organisms are likely.

## TABLE A
## GENERIC DATA REQUIREMENTS FOR DICOFOL

| Data Requirements | Composition 1/ | Use Pattern 2/ | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/ |
|---|---|---|---|---|---|
| **§158.150 Plant Protection** | | | | | |
| 121-1 - TARGET AREA PHYTOTOXICITY | EP | - | - | - | No 4/ |
| NONTARGET AREA PHYTOTOXICITY | | | | | |
| TIER I | | | | | |
| 122-1 - Seed Germination/ Seedling Emergence | TGAI | - | - | - | No 4/ |
| 122-1 - Vegetative Vigor | TGAI | - | - | - | No 4/ |
| 122-2 - Aquatic Plant Growth | TGAI | - | - | - | No 4/ |
| TIER II | | | | | |
| 123-1 - Seed Germination/ Seedling Emergence | TGAI | - | - | - | No 4/ |
| 123-1 - Vegetative Vigor | TGAI | - | - | - | No 4/ |
| 123-2 - Aquatic Plant Growth | TGAI | - | - | - | No 4/ |
| TIER III | | | | | |
| 124-1 - Terrestrial Field | TEP | - | - | - | No 4/ |
| 124-2 - Aquatic Field | TEP | - | - | - | No 4/ |

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product.
EP = End-use product.

2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food Crop; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

3/ Data must be submitted no later than December, 1986.

4/ This study is not required because dicofol has not been shown to cause phytotoxicity problems.

## TABLE A
## GENERIC DATA REQUIREMENTS FOR DICOFOL

| Data Requirement | Composition 1/ | Use Pattern 2/ | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/ |
|---|---|---|---|---|---|
| §158.155 Nontarget Insect | | | | | |
| NONTARGET INSECT TESTING - POLLINATORS: | | | | | |
| 141-1 - Honey bee acute contact $LD_{50}$ | TGAI | A,B,H | Yes | 05001991, 05008989<br>05008900, 05009244 | No |
| 141-2 - Honey bee - toxicity of residues on foliage | - | - | - | - | No 4/ |
| 141-3 - Wild bees important in alafala pollination - toxicity of residues on foliage | - | - | - | - | No 4/ |
| 141-4 - Honey bee subacute feeding study | - | - | - | - | Reserved 5/ |
| 141-5 - Field testing for pollinators | - | - | - | - | No 4/ |
| NONTARGET INSECT TESTING - AQUATIC INSECTS: | | | | | |
| 142-1 - Acute toxicity to aquatic insects | - | - | - | - | Reserved 5/ |
| 142-2 - Aquatic insect life-cycle study | - | - | - | - | Reserved 5/ |
| 142-3 - Simulated or actual field testing for aquatic insects | - | - | - | - | Reserved 5/ |

## TABLE A
## GENERIC DATA REQUIREMENTS FOR DICOFOL

| Data Requirement | Composition 1/ | Use Pattern 2/ | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/ |
|---|---|---|---|---|---|
| §158.155 Nontarget Insect | | | | | |
| 143-1 thru 143-3 - NONTARGET INSECT TESTING-PREDATORS AND PARASITES | - | - | - | - | Reserved 5/ |

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1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product.

2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop: D=Aqautic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

3/ Data must be submitted no later than December, 1986.

4/ Although dicofol is registered for use on alfalfa grown for seed, dicofol has been shown to be relatively nontoxic to bees. This study is not required.

5/ Reserved pending the Agency's decision whether or not to establish this study as a data requirement.

## TABLE B
## PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING DICOFOL

| Data Requirement | Composition[1/] | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2/] |
|---|---|---|---|---|
| §158.120 Product Chemistry | | | | |
| Product Identity | | | | |
| 61-1 - Identity of Ingredients | MP | No | - | Yes[3/] |
| 61-2 - Statement of Composition | MP | No | - | Yes[3/] |
| 61-3 - Discussion of Formation of Impurities | MP | No | Confidential Statement of Formula | Yes[4/] |
| Analysis and Certification of Product Ingredients: | | | | |
| 62-1 - Preliminary Analysis | MP | No | | Yes[5/] |
| 62-2 - Certification of Limits | MP | Partially | Confidential Statement of Formula | Yes[6/] |
| 62-3 - Analytical Methods for Enforcement of Limits | | | | |
| - Active Ingredient | MP | Yes | 05005142, 00004348[a/]<br>05014643, 05017499<br>00004340, 05004951<br>05005964, 05006333<br>05005167, 00004336[b/]<br>05015278, 05020221<br>05005274, 05004878<br>05005279, 05015625<br>05017892 | No |
| - Impurities | MP | Yes | 05004176 | No |

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING DICOFOL

| Data Requirement | Composition [1/] | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? [2/] |
|---|---|---|---|---|
| Physical and Chemical Characteristics | | | | |
| 63-2 - Color | MP | Partially | 00004358[c/], 00004339[d/] | Yes[7/] |
| 63-3 - Physical State | MP | Partially | 00004358[c/], 00004339[d/] | No |
| 63-4 - Odor | MP | No | | Yes |
| 63-7 - Density, bulk density, or specific gravity | MP | Partially | 00004358[c/], 00004339[d/] | Yes[7/] |
| 63-12 - pH | - | - | - | No[8/] |
| 63-14 - Oxidizing or reducing potential | MP | No | | Yes |
| 63-15 - Flammability | MP | Yes | 00004358[c/], 00004339[d/] | Yes[7/] |
| 63-16 - Explodability | MP | No | | Yes |
| 63-17 - Storage Stability | MP | Yes | 00004358[c/], 00004339[d/] | Yes[7/] |
| 63-18 - Viscosity | - | | | No[9/] |
| 63-19 - Miscibility | MP | No | | Yes |
| Other Requirements | | | | |
| 64- 1 - Submittal of Samples | Choice | | | |

1/ Composition: MP = Manufacturing-use product; Choice = Choice of several test substances determined on a case-by-case basis.

2/ Data must be submitted no later than April, 1984.

3/ Updated information must be supplied by all companies on identity and quantity of impurities and inert ingredients. Special attention must be given to identifying and quantifying the DDT impurities. The name and address of the producer of the starting materials, the manufacturing process, and the reaction conditions needed.

4/ Special testing is required on the impurity known as Cl-DDT. These tests are the octanol-water partitian coefficient, water solubility, and vapor pressure.

5/ Five or more representative samples should be analyzed for the amount of active ingredient and each impurity present in the technical material for which a certified limit is required.

6/ Upper and lower limits must be provided and certified for the dicofol concentrations and each impurity > 0.1 percent.

7/ Aceto Chemical did not submit any physical/chemical properties. Rohm & Haas and Makhteshim Beer-Shiva did report some physical/chemical properties for the technical product.

8/ Not soluble in water, therefore no pH data are required.

9/ Not applicable because the material is not a liquid.

a/ Data submitted by Intrachem, S.A. These data may be compensable.

b/ Data submitted by Aceto Chemical Company. These data may be compensable.

c/ Data submitted by Rohm and Haas Company. These data may be compensable.

d/ Data submitted by Makhteshim Beer-Sheva Chemical Works, Limited. These data may be compensable.

## TABLE B
## PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING DICOFOL

| Data Requirement | Composition [1] | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? |
|---|---|---|---|---|
| §158.135 Toxicology | | | | |
| ACUTE TESTING | | | | |
| 81-1 - Oral $LD_{50}$ - Rat | MP | Yes | 00004373; 00004365<br>05002571; 00004374 | No |
| 81-2 - Dermal $LD_{50}$ | MP | Yes | 00004366 | No |
| 81-3 - Inhalation $LC_{50}$ - Rat | MP | No | | Yes |
| 81-4 - Primary Eye Irritation - Rabbit | MP | No | | Yes [3] |
| 81-5 - Primary Dermal Irritation | MP | No | | Yes |
| 81-6 - Dermal Sensitization | MP | No | | Yes |

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[1] Composition: MP = Manufacturing-use product.

[2] Data must be submitted no later than December, 1986.

[3] Based on the primary eye irritation data available on formulation intermediates, manufacturing-use dicofol is considered a potentially severe eye irritant. If the registrants agree that it is a severe eye irritant, the formulation intermediate data will suffice. Otherwise, the study must be conducted with a manufacturing-use product.

## IV. SUBMISSION OF REVISED LABELING AND PACKAGING INFORMATION

Note: This chapter applies only to manufacturing-use products, not end-use products.

The Agency requires applicants for registration or reregistration to ensure that each label (1) contains accurate, complete, and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients, and (2) incorporates labeling format and terminology which are sufficiently standardized to avoid user confusion.

As part of your application, you will be required to submit draft labeling consistent with: applicable product-specific data; the precautionary statements and use directions; and the regulations concerning classification [40 CFR §162.11(c)], packaging [40 CFR §162.16], and labeling [40 CFR §162.10], as indicated by the following paragraphs of this chapter of the guidance document.

You will be informed later when you must submit the revised labeling set forth in this guidance package.

### A. Label Contents

40 CFR §162.10 requires that certain specific labeling statements must appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to Tables D, E, and F (Appendix IV-2).

Item 1. PRODUCT NAME - The name, brand, or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading. [40 CFR §162.10(b)]

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text. [40 CFR §162.10(c)]

Item 3. NET CONTENTS - A net content statement is required on all labels. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be stated in terms of weight, expressed as avoirdupois pounds and ounces, and stated in terms of the largest suitable unit, i.e., "1 pound 10 ounces" rather than "26 ounces." In addition to the required units specified, net contents may be expressed in metric units. [40 CFR §162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR §162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR §162.10(f)]

Item 6. INGREDIENT STATEMENT - An ingredient statement is required on the front panel and must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredient statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 162.10(g)]

Item 6A. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - All labels are required to have precautionary statements grouped together on the front panel, preferably within a block outline. The table below shows the minimum type size requirements on various size labels, as set forth in the Regulations.

| Size of Label on Front Panel in Square Inches | Signal Word as Required Minimum Type Size All Capitals | "Keep Out of Reach of Children" as Required |
|---|---|---|
| 5 and under | 6 point | 6 point |
| above 5 to 10 | 10 point | 6 point |
| above 10 to 15 | 12 point | 8 point |
| above 15 to 30 | 14 point | 10 point |
| over 30 | 18 point | 12 point |

Item 7A. CHILD HAZARD WARNING STATEMENT - All labels are required to have the statement "Keep Out of Reach of Children" located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR §162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (Caution, Warning, or Danger) is required on the front panel immediately below the child hazard warning statement. [40 CFR §162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, inhalation, or dermal toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word poison. [40 CFR §162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR §162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR §162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements as listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR §162.10 (h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions taken to avoid accident, injury or damage. [40 CFR §162.10 (h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR §162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD

1. Flammability statement. Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in Appendix IV-3. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

2. Criteria for declaration of non-flammability. The following criteria will be used to determine if a product is non-flammable:

   a. A "non-flammable gas" is a gas (or mixture of gases) that will not ignite when a lighted match is placed against the open cylinder valve.

   b. A "non-flammable liquid" is one having a flashpoint greater than 350°F (177°C) as determined by the method specified in 40 CFR §163.61-8(c)(13)(ii) of Subpart D.

   c. A "non-flammable aerosol" is one which meets the following criteria:

      i. The flame extension is zero inches, using the method specified in 40 CFR §163.61-8(c)(13)(ii);

      ii. There is no flash back; and

      iii. The flashpoint of the non-volatile liquid component is greater than 350°F (177°C), determined by the method specified in 40 CFR §163.61-8(c)(13)(i).

3. Declaration of non-flammability. Products which meet the criteria for non-flammability specified above may bear the notation "non-flammable" or "nonflammable (gas, liquid, etc.)" on the label.

   It may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) in any way that may detract from precaution.

4. Other physical/chemical hazard statements. When chemistry data submitted in accordance with 40 CFR §163.61-10(c) demonstrate hazards of a physical or chemical nature other than flammability, appropriate statements of hazard will be prescribed. Such statements may address hazards of explosivity, oxidizing or reducing capability, or mixing with other substances to produce toxic fumes.

Item 9. MISUSE STATEMENT - The following statement is required on your label: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." [40 CFR §162.10(1)(2)(ii)]

Item 10A. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. Make certain that the statement you use pertains specifically to your product. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix IV-5 for the latest specific storage and disposal product label statements.

Item 10B. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR §162.10]

## B. Collateral Information

Bulletins, leaflets, circulars, brochures, data sheets, flyers, and other graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

## V. INSTRUCTIONS FOR SUBMISSION

All applications prepared in response to this Notice should be addressed as follows:

Jay Ellenberger, Product Manager 12
Phone No. (703) 557-2386
Registration Division (TS-767)
Office of Pesticide Programs
Environmental Protection Agency
Washington, D.C. 20460

For each product for which continued registration is desired:

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet" EPA Form 8580-1. Refer to Appendix II-2 with appropriate attachments.

2. Within 6 months from receipt of this document registrants must submit:

   a. Confidential Statement of Formula, EPA Form 8570-4.

   b. Product Specific Data Report, EPA Form 8580-4 (Appendix III-1).

   c. Two copies of any required product-specific data.

3. Within the time set forth in Table A, all generic data must be submitted by the affected registrant(s).

Note: If for any reason any required test is delayed or aborted so that meeting the agreed submission time will be delayed, notify the Product Manager listed above.

You will be informed at a later date when you must submit your Application for Amended Pesticide Registration (EPA Form 8570-1) and the revised labeling set forth in this guidance package.

## Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

    a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

## OFFICE OF PESTICIDE PROGRAMS
## REGISTRATION GUIDANCE DOCUMENT BIBLIOGRAPHY
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Appendix II

*OMB Approval No. 2000-0468 (Expires 12-31-83)*

# FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET

**EPA REGISTRATION NO.**

**PRODUCT NAME**

**APPLICANT'S NAME**

**DATE GUIDANCE DOCUMENT ISSUED**

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

**NAME OF OTHER REGISTRANT**

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

| | | |
|---|---|---|
| **REGISTRANT'S AUTHORIZED REPRESENTATIVE** | **SIGNATURE** | **DATE** |

EPA Form 8580-1 (10-82)

Appendix III

*OMB Approval No. 2000-0468 (Expires: 12-31-83)*

## CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

*(To qualify, certify ALL four items)*

| | |
|---|---|
| 1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient: | **GUIDANCE DOCUMENT DATE** |
| | **ACTIVE INGREDIENT** |
| **NAME OF FIRM** | **EPA COMPANY NUMBER** |
| | |
| | |
| | |
| | |

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

| NAME OF FIRM | DATE OF OFFER |
|---|---|
| | |
| | |
| | |
| | |

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

| TYPED NAME | SIGNATURE | DATE |
|---|---|---|
| | | |

EPA Form 8580-6 (10-82)

## PRODUCT SPECIFIC DATA REPORT

EPA Registration No.________________Guidance Document for________________

Date________________

| Registration Guideline No. | Name of Test | Test not required for my product listed above (check below) | I am complying with data requirements by | | (For EPA Use Only) Accession Numbers Assigned |
|---|---|---|---|---|---|
| | | | Citing MRID# | Submitting Data (Attached) | |
| §158.20 PRODUCT CHEMISTRY | | | | | |
| 61-1 | Identity of ingredients | | | | |
| 61-2 | Statement of composition | | | | |
| 61-3 | Discussion of formation of ingredients | | | | |
| 62-1 | Preliminary analysis | | | | |
| 62-2 | Certification of limits | | | | |
| 62-3 | Analytical methods for enforcement limits | | | | |
| 63-2 | Color | | | | |
| 63-3 | Physical state | | | | |
| 63-4 | Odor | | | | |
| 63-5 | Melting point | | | | |
| 63-6 | Boiling point | | | | |
| 63-7 | Density, bulk-density, or specific gravity | | | | |
| 63-8 | Solubility | | | | |
| 63-9 | Vapor pressure | | | | |
| 63-10 | Dissociation constant | | | | |
| 63-11 | Octanol/water partition coefficient | | | | |
| 63-12 | pH | | | | |
| 63-13 | Stability | | | | |
| 63-14 | Oxidizing/reducing reaction | | | | |
| 63-15 | Flammability | | | | |
| 63-16 | Explodability | | | | |
| 63-17 | Storage stability | | | | |
| 63-18 | Viscosity | | | | |

| | | | | | |
|---|---|---|---|---|---|
| 63-19 | Miscibility | | | | |
| 63-20 | Corrosion characteristics | | | | |
| 63-21 | Dielectric breakdown voltage | | | | |
| §158.135 TOXICOLOGY | | | | | |
| 81-1 | Acute oral LD-50, rat | | | | |
| 81-2 | Acute dermal LD-50 | | | | |
| 81-3 | Acute inhalation, LC-50 rat | | | | |
| 81-4 | Primary eye irritation, rabbit | | | | |
| 81-5 | Primary dermal irritation | | | | |
| 81-6 | Dermal sensitization | | | | |

APPENDIX V-2

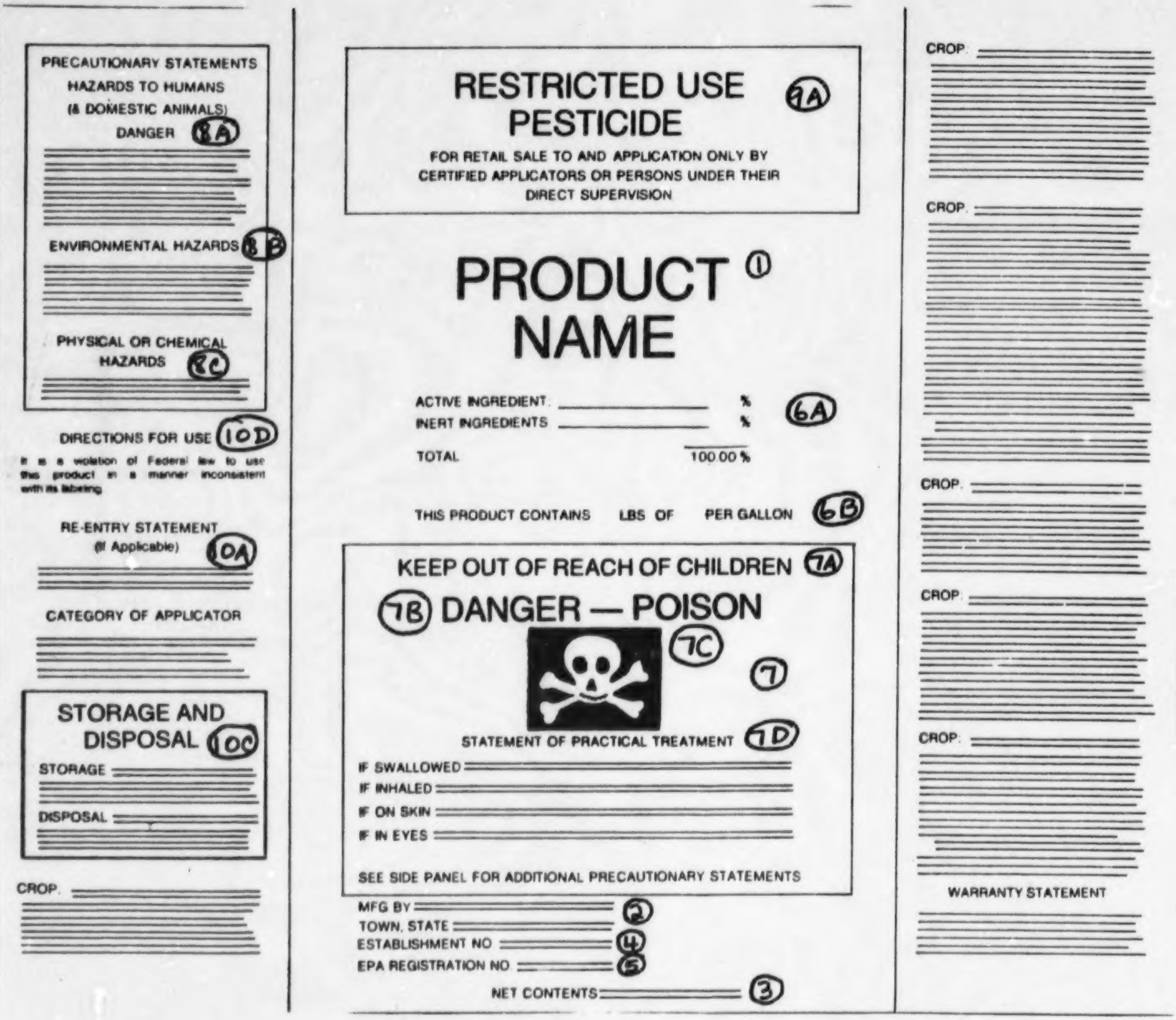
## LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (REFER TO THE SAMPLE LABELS FOLLOWING)

| ITEM | LABEL ELEMENT | APPLICABILITY OF REQUIREMENT | PLACEMENT ON LABEL |  | COMMENTS |
|---|---|---|---|---|---|
|  |  |  | REQUIRED | PREFERRED |  |
| 1 | Product name | All products | Front panel | Center front panel |  |
| 2 | Company name and address | All products | None | Bottom front panel or end of label text | If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc. |
| 3 | Net contents | All products | None | Bottom front panel or end of label text | May be in metric units in addition to U.S. units |
| 4 | EPA Est. No. | All products | None | Front panel | Must be in similar type size and run parallel to other type. |
| 5 | EPA Reg. No. | All products | None | Front panel, immediately before or following Reg. No. | May appear on the container instead of the label. |
| 6A | Ingredients statement | All products | Front panel | Immediately following product name | Text must run parallel with other text on the panel. |
| 6B | Pounds/gallon statement | Liquid products where dosage given as lbs. ai/unit area | Front panel | Directly below the main ingredients statement |  |
| 7 | Front panel precautionary statements | All products | Front panel |  | All front panel precautionary statements must be grouped together, preferably blocked. |
| 7A | Keep Out of Reach of Children (Child hazard warning) | All products | Front panel | Above signal word | Note type size requirements. |
| 7B | Signal word | All products | Front panel | Immediately below child hazard warning | Note type size requirements. |

| ITEM | LABEL ELEMENT | APPLICABILITY OF REQUIREMENT | PLACEMENT ON LABEL |  | COMMENTS |
|---|---|---|---|---|---|
|  |  |  | REQUIRED | PREFERRED |  |
| 7C | Skull & cross-bones and word POISON (in red) | All products which are Category I based on oral, dermal, or inhalation toxicity | Front panel | Both in close proximity to signal word |  |
| 7D | Statement of practical treatment | All products in Categories I, II, and III | Category I:<br>Front panel unless referral statement is used.<br>Others:<br>Grouped with side panel precautionary statements. | Front panel for all. |  |
| 7E | Referral statement | All products where precautionary labeling appears on other than front panel. | Front panel |  |  |
| 8 | Side/back panel precautionary statements | All products | None | Top or side of back panel preceding directions for use | Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked. |
| 8A | Hazards to humans and domestic animals | All products in Categories I, II, and III | None | Same as above | Must be preceded by appropriate signal word. |
| 8B | Environmental hazards | All products | None | Same as above | Environmental hazards include bee caution where applicable. |

| ITEM | LABEL ELEMENT | APPLICABILITY OF REQUIREMENT | PLACEMENT ON LABEL | | COMMENTS |
|---|---|---|---|---|---|
| | | | REQUIRED | PREFERRED | |
| 8C | Physical or chemical hazards | All pressurized products, others with flash points under 150°F | None | Same as above | |
| 9A | Restricted block | All restricted products | Top center of front panel | Preferably blocked | Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word. |
| 9C | Misuse statement | All products | Immediately following statement of classification or ahead of directions for use | | |
| 10A | Re-entry statement | All cholinesterase inhibitors | In the directions for use | Immediately after misuse statement | |
| 10C | Storage and disposal block | All products | In the directions for use | Immediately before specific directions for use or at the end of directions for use | Must be set apart and clearly distinguishable from from other directions for use. |
| 10D U.S. | Directions for use | All products | None | None | May be in metric as well as U.S. units |

## RESTRICTED USE PESTICIDE



PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
(& DOMESTIC ANIMALS)
DANGER (8A)

ENVIRONMENTAL HAZARDS (8B)

PHYSICAL OR CHEMICAL HAZARDS (8C)

DIRECTIONS FOR USE (10D)

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

RE-ENTRY STATEMENT
(If Applicable) (10A)

CATEGORY OF APPLICATOR

STORAGE AND DISPOSAL (10C)

STORAGE

DISPOSAL

CROP:

RESTRICTED USE PESTICIDE (9A)

FOR RETAIL SALE TO AND APPLICATION ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION

PRODUCT NAME ①

ACTIVE INGREDIENT: ______ %
INERT INGREDIENTS ______ % (6A)
TOTAL 100.00 %

THIS PRODUCT CONTAINS LBS OF PER GALLON (6B)

KEEP OUT OF REACH OF CHILDREN (7A)

(7B) DANGER — POISON

(7C) ⑦

STATEMENT OF PRACTICAL TREATMENT (7D)

IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

MFG BY ②
TOWN, STATE
ESTABLISHMENT NO ④
EPA REGISTRATION NO ⑤
NET CONTENTS ③

CROP:

CROP:

CROP:

CROP:

CROP:

WARRANTY STATEMENT

# STORAGE AND DISPOSAL INSTRUCTIONS FOR PESTICIDES

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL." The STORAGE AND DISPOSAL heading must appear in the minimum type size listed below:

| Size of label front panel in square inches | Required type size for the heading STORAGE AND DISPOSAL (all capitals) |
|---|---|
| 10 and under | .6 point |
| Above 10 to 15 | .8 point |
| Above 15 to 30 | 10 point |
| Over 30 | 12 point |

Storage and disposal instructions must be set apart and clearly distinguishable from other directions for use. Blocking storage and disposal statements with a solid line is suggested as a means of increasing their prominence.

## A. Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

B. Pesticide Disposal Instructions:

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients appearing on the "Acutely Hazardous" Commercial Pesticide Products List (RCRA "E" List) at the end of this appendix or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, skin or eye irritation potential, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

   "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

   The labels of all products, except those intended for domestic use, containing active or inert ingredients that appear on the "Toxic" Commercial Pesticide Products List (RCRA "F" List) at the end of this appendix or presently meet any of the criteria in Subpart C, 40 CFR 261 for a hazardous waste must bear the following pesticide disposal statement:

"Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

"Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

3. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

C. Container Disposal Instructions

The label of each product must bear container disposal instructions appropriate to the type of container.

1. All products intended for domestic use must bear one of the following container disposal statements:

| Container Type | Statement |
|---|---|
| Non-aerosol products (bottles, cans, jars) | Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash. |
| Non-aerosol products (bags) | Do not reuse bag. Discard bag in trash. |
| Aerosol products | Replace cap and discard containers in trash. Do not incinerate or puncture. |

2. The labels for all other products must bear container disposal instructions, based on container type, listed below:

| Container Type | Statement |
|---|---|
| Metal containers (non-aerosol) | Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. |
| Plastic containers | Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. |
| Glass containers | Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures. |

| Container Type | Statement |
|---|---|
| Fiber drums with liners | Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner. |
| Paper and plastic bags | Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke. |
| Compressed gas cylinders | Return empty cylinder for reuse (or similar wording). |

[1] Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

2. The labels for all other products must bear container disposal instructions, based on container type, listed on the first page of this Appendix.

Pesticides that are hazardous wastes under 40 CFR 261.33(e) and (f) when discarded.

## "Acutely Hazardous" Commercial Pesticides (RCRA "E" List) Active Ingredients, (no inerts):

Acrolein
Aldicarb
Aldrin
Allyl alcohol
Aluminum phosphide
4-Aminopyridine
Arsenic acid
Arsenic pentoxide
Arsenic trioxide
Calcium cyanide
Carbon disulfide
p-Chloroaniline
Cyanides (soluble cyanide salts, not specified elsewere)
Cyanogen chloride
2-Cyclohexyl-4,6-dinitrophenol
Dieldrin
0,0-Diethyl S-[2-ethylthio)ethyl] phosphorodithioate
    (disulfoton, Di-Syston)
0,0-Diethyl 0-pyrazinyl phosphorothioate (Zinophos)
Dimethoate
0,0-Dimethyl 0-p-nitrophenyl phosphorothioate (methyl parathion)
4,6-Dinitro-o-cresol and salts
4,6-Dinitro-o-cyclohexylphenol
2,4 Dinitrophenol
Dinoseb
Endosulfan
Endothall
Endrin
Famphur
Fluoroacetamide
Heptachlor
Hexanethyl tetraphosphate
Hydrocyanic acid
Hydrogen cyanide
Methomyl
alpha-Naphthylthiourea (ANTU)
Nicotine and salts
Octamethylpyrophosphoramide (OMPA, schradan)
Parathion

## "Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
## Active Ingredients continued:

Phenylmercuric acetate (PMA)
Phorate
Potassium cyanide
Propargyl alcohol
Sodium azide
Sodium cyanide
Sodium fluoroacetate
Strychnine and salts
0,0,0,0-Tetraethyl dithiopyrophosphate (sulfotepp)
Tetraethyl pyrophosphate
Thallium sulfate
Thiofanox
Toxaphene
Warfarin
Zinc phosphide

---

There are currently no inert ingredients for commercial pesticides on the "Acutely Hazardous" List (RCRA "E" List).

## "Toxic" Commercial Pesticide Products (RCRA "F" List)
## Active Ingredients:

Acetone
Acrylonitrile
Amitrole
Benzene
Bis(2-ethylhexyl)pthalate
Cacodylic acid
Carbon tetrachloride
Chloral (hydrate)
Chlordane (technical)
Chlorobenzene
4-Chloro-m-cresol
Chloroform
o-Chlorophenol
4-Chloro-o-toluidine hydrochloride
Creosote
Cresylic acid
Cyclohexane
Decachlorooctahydro-1,3,4-metheno-2H-cyclobuta[c,d]-pentalen-2-one
    (kepone, chlordecone)
1,2-Dibromo-3-chloropropane (DBCP)
Dibutyl phthalate
S-3,3-(Dichloroallyl diisopropylthiocarbamate (diallate, Avadex)
o-Dichlorobenzene
p-Dichlorobenzene
Dichlorodifluoromethane (Freon 12®)
3,5-Dichloro-N-(1,1-dimethyl-2-propynyl) benzamide (pronamide,Kerb)
Dichloro diphenyl dichloroethane (DDD)
Dichloro diphenyl trichloroethane (DDT)
Dichlorethyl ether
2,4-Dichlorophenoxyacetic, esters and salts (2,4-D)
1,2-Dichloropropane
1,3-Dichloropropane (Telone)
Dimethyl phthalate
Ethyl acetate
Ethyl 4,4'-dichlorobenzilate (chlorobenzilate)
Ethylene dibromide (EDB)
Ethylene dichloride
Ethylene oxide
Formaldehyde
Furfural
Hexachlorobenzene
Hexachlorocyclopentadiene
Hexachloroethane
Hydrofluoric acid

## "Toxic" Commercial Pesticide Products (RCRA "F" List)
## Active Ingredients:

Isobutyl alcohol
Lead acetate
Lindane
Maleic hydrazide
Mercury
Methyl alcohol
Methyl bromide
Methyl chloride
2,2'-Methylenebis (3,4,6-trichlorophenol) (hexachlorophene)
Methylene chloride
Methyl ethyl ketone
4-Methyl-2-pentanone (methyl isobutyl ketone)
Naphthalene
Nitrobenzene
p-Nitrophenol
Pentachloroethane
Pentachloronitrobenzene (PCNB)
Pentaclorophenol
Phenol
Phosphorodithioic acid, 0,0-diethyl, methyl ester
Propylene dichloride
Pyridine
Resorcinol
Safrole
Selenium disulfide
Silvex
1,2,4,5-Tetrachlorobenzene
1,1,2,2-Tetrachloroethane
Tetrachloroethylene
2,3,4,6-Tetrachlorophenol
Thiram
Toluene
1,1,1-Trichloroethane
Trichloroethylene
Trichloromonofluoromethane (Freon 11®)
2,4,5-Trichlorophenol
2,4,6-Trichlorophenol
2,4,5-Trichlorophenoxyacetic acid (2,4,5-T)
Xylene

## "Toxic" Commercial Pesticide Products (RCRA "F" List)

### Inert Ingredients:

- Acetone
- Acetonitrile
- Acetophenone
- Acrylic acid
- Aniline
- Benzene
- Chlorobenzene
- Chloroform
- Cyclohexane
- Cyclohexanone
- Dichlorodifluoromethane (Freon 12®)
- Diethyl phthalate
- Dimethylamine
- Dimethyl phthalate
- 1,4-Dioxane
- Ethylene oxide
- Formaldehyde
- Formic acid
- Isobutyl alcohol
- Meleic anhydride
- Methyl alcohol (methanol)
- Methyl ethyl ketone
- Methyl methacrylate
- Naphthalene
- Saccharin and salts
- Thiourea
- Toluene
- 1,1,1-Trichloroethane
- 1,1,2-Trichloroethane
- Trichlorofluoromethane (Freon 11®)
- Vinyl chloride
- Xylene

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

CERTIFIED MAIL

SUBJECT: Initiation of Reregistration and Special Review Process for Pesticide Products Containing Dicofol as the Single Active Ingredient

Dear Registrant:

In accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, EPA's Office of Pesticide Programs has begun the reregistration process for pesticide products containing dicofol. Significant changes to the statute were made in 1972, 1975, and 1978; thus, current requirements may be substantially different from those in effect at the time your product(s) were registered. The first phase of reregistration requires that you (1) make a commitment to the Agency regarding data development and (2) subsequently submit revised product labeling and associated information. At the same time, a Special Review is being initiated which may result in cancellation of your product(s).

This mailing contains the Guidance Document for preparation of submissions, as well as a listing of your affected product(s) (Attachment A), and a separate list of registrants with products subject to this standard and which contain this active ingredient (Attachment B). The latter list is for the purpose of cooperative data development.

The Guidance Document sets out the Agency's evaluation of all available data pertaining to the subject chemical and its registered uses, and its rationale for the regulatory actions being taken at this time. Additionally, the Guidance Document contains instructions describing the steps you must take to maintain registration for your product(s). Products not brought into compliance with the Guidance Document, as supplemented by subsequent information from EPA about compliance with certain data support requirements, will be subject to suspension and/or cancellation.

Specifically, the enclosed Guidance Document does the following:

1. Introduces the purpose of this document.
2. Explains the Agency's policy regarding data submission and identifies, in table format, the data that must be submitted to complete the Agency's evaluation of each product. In addition, a bibliography identifying the data which is considered part of the data base supporting the registration standard is included.
3. Sets out time-frames for submission of required data.
4. Explains how to revise labeling for maufacturing-use and end-use products. Labeling is required within 90 days of receipt of this notice. Existing stocks of products covered by this Guidance Document, related brochures, technical pamphlets and similar materials must be "sticker" labeled to comply with all label requirements within 270 days after receipt of this Document.
5. Provides submission instructions.
6. Summarizes the Agency's assessment of risks and benefits of dicofol and describes the Special Review process.

Because of the variety and complexity of the requirements, and the short statutory time-frames available for certain actions, it is essential that you understand the specific requirements and procedures in order that you may respond in a correct and timely manner. Since a part of these requirements is under Section 3(c)(2)(B) of FIFRA, your first response may be required within 90 days from receipt of this letter. Please note that if you do not respond or do not comply fully with the requirements, your application may be rejected or your product registration cancelled or suspended.

If, after reviewing this material, you do not understand what you must do or how or when you must respond, please contact the Product Manager listed below who will assist you in every reasonable way. If you wish to discuss the data requirements or request that certain data be waived, you must write to the Agency and indicate those data requirements with which you take issue and your rationale for doing so. After the Agency has had a chance to review your submission, the Product Manager will contact you to set up a meeting for the purpose of resolving all issues relative to data requirements.

Please note that this guidance document will eventually be supplemented by EPA with additional information about compliance with data support requirements. In Monsanto v. Administrator, EPA was recently enjoined by the District Court for the Eastern District of Missouri from implementing in any way the "mandatory data licensing" aspects of §3(c)(1)(D) of FIFRA. EPA is assessing the implications of the injunction for the reregistration process. Because of this unresolved situation, EPA has decided to proceed with the requirements in this guidance package which do not relate to the "data licensing" issue and to supplement the package with additional guidance when circumstances permit.

The Agency has determined that dicofol has exceeded the criteria established in 40 CFR 162.11(a) for unreasonable adverse effects on the environment. The Agency has also identified data gaps which, when filled, will refine the environmental fate, ecological effects, and human toxicology potential of dicofol and its DDT related contaminants. Finally, the Agency is initiating a Special Review with the publication of this Guidance Document to examine the risks and benefits of dicofol use and to propose regulatory actions. The procedures and rationale for these actions are outlined in the Guidance Document.

If you have any questions concerning this Guidance Document, you may contact the Product Manager listed below:

Jay Ellenberger (PM Team 12)
Registration Division (TS-767)
Office of Pesticide Programs
Environmental Protection Agency
1921 Jefferson Davis Hwy
Arlington, VA 22202

Sincerely,

Douglas D. Campt, Director
Registration Division (TS-767)

Enclosure

## ATTACHMENT A

## PRODUCTS AFFECTED BY THIS REREGISTRATION PROCESS

Following is a list of your products affected by this reregistration process. If this list is incomplete or inaccurate in any way, please notify the Product Manager (PM) identified in the letter.

This letter was sent to:

Rohm & Haas Company
P.O. Box 1348
Philadelphia, PA 19105

| | |
|---|---|
| 707-58 | Kelthane W |
| 707-59 | Kelthane EC |
| 707-66 | Kethane Dust Base- For Manufacturing Use only |
| 707-73 | Kelthane MF |
| 707-76 | Kelthane AP |
| 707-89 | Kelthane 35 Agricultural Miticide Wettable Powder |
| 707-107 | Kelthane Technical |
| 707-114 | Kelthane Solution |
| 707-119 | Kelthane 60 |
| 707-164 | Kelthane 4F |

Tricon International
c/o Ralph A. Roane
P.O.Box 1103
Clermont, FL 32711

| | |
|---|---|
| 44600-1 | Dicofol Technical |
| 44600-4 | Tower Dicofol 1.6-EC |

Aceto Chemical Company
126-02 Northern Blvd.
Flushing, NY 11368

Attn: Mr. Baldi

| | |
|---|---|
| 2749-286 | Dicofol Technical Miticide |

Agan Chemical Mfgrs., Ltd.
c/o Solchem Div. of Koor
2 Park Ave.
New York, NY 10016

| | |
|---|---|
| 11603-19 | Mitigan 42 E.C. Dicofol |
| 11603-20 | Mitigan 18.5% W.P. Dicofol |

Drexel Chemical Co.
2487 Pennsylvania St.
Box 9306
Memphis, TN 38109

| | |
|---|---|
| 19713-77 | Drexel Dicofol Technical |
| 19713-98 | Drexel Dicofol E.C. |
| 19713-137 | Drexel Dicofol Technical |
| 19713-139 | Drexel Dicofol 42 EC |

Ida, Inc.
2487 Pennsylvania St.
Box 9483
Memphis, TN 38109

45115-49 Ida Dicofol Technical

Makhteshim Beer-Sheva
Chemical Works, Ltd.
c/o Solchem Div. of Solcoor
2 Park Ave.
New York, NY 10016

11678-7 Acarin (Dicofol) Technical